To reauthorize the Select Agent Program by amending the Public Health Service Act and the Agricultural Bioterrorism Protection Act of 2002 and to improve oversight of high containment laboratories.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 26, 2009

Ms. ARMAN (for herself and Mr. ROGERS of Michigan) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Agriculture and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To reauthorize the Select Agent Program by amending the Public Health Service Act and the Agricultural Bioterrorism Protection Act of 2002 and to improve oversight of high containment laboratories.

1 Be it enacted by the Senate and House of Representa-
2 tives of the United States of America in Congress assembled,

3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

4 (a) Short Title.—This Act may be cited as the
5 “Select Agent Program and Biosafety Improvement Act
6 of 2009”.


(b) **TABLE OF CONTENTS.**—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings.

**TITLE I—SELECT AGENT PROGRAM REAUTHORIZATION**

Sec. 101. Reauthorization of select agent program.
Sec. 102. Select agent program review.
Sec. 103. Revision of the list of biological agents and toxins.
Sec. 104. Sharing information with trusted State partners.
Sec. 105. Improvements to inventorying and monitoring of agents.
Sec. 106. Smallpox definition clarification.
Sec. 107. Plan for surge in samples of biological agents and toxins.

**TITLE II—BIOSAFETY IMPROVEMENTS**

Sec. 201. Improvement of oversight of biocontainment laboratories.
Sec. 202. Improvement of training for laboratory personnel.
Sec. 203. Biological laboratory incident reporting system.

**SEC. 2. FINDINGS.**

Congress finds the following:

(1) The Centers for Disease Control and Prevention regulates the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety.

(2) The Animal and Plant Health Inspection Service regulates the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products.

(3) As of February 2009, there are 82 select agents and toxins, 13 of which are found naturally in the United States.
(4) As of February 2009, there are 336 entities registered with the Centers for Disease Control and Prevention to work with select agents and toxins and 64 entities registered with the Animal and Plant Health Inspection Service. There are 10,463 individuals approved to work with select agents and toxins through the Centers for Disease Control and Prevention and 4,149 through the Animal and Plant Health Inspection Service.

(5) Biocontainment laboratories are used by scientists to study infectious materials safely and effectively. Laboratory biological research is categorized by the safety level at which it is performed. There are 4 safety levels, termed Biosafety Level (BSL) 1 through 4.

**TITLE I—SELECT AGENT PROGRAM REAUTHORIZATION**

**SEC. 101. REAUTHORIZATION OF SELECT AGENT PROGRAM.**

(a) **Reauthorization of Select Agent Program.—**

(1) **Amendment to the Public Health Service Act.**—Section 351A(m) of the Public Health Service Act (42 U.S.C. 262a(m)) is amended by striking “2002 through 2007” and inserting “2009 through 2013”.
(2) Amendment to the Agricultural Bio-
terrorism Protection Act of 2002.—Section
212(m) of the Agricultural Bioterrorism Protection
Act of 2002 (7 U.S.C. 8401(m)) is amended by
striking “2002 through 2007” and inserting “2009
through 2013”.

(b) Appropriate Training.—

(1) Amendment to the Public Health
Service Act.—Section 351A(e)(2)(A) of the Public
Health Service Act (42 U.S.C. 262a(e)(2)(A)) is
amended by inserting “, and appropriate training,”
after “have a legitimate need”.

(2) Amendment to the Agricultural Bio-
terrorism Protection Act of 2002.—Section
212(e)(2)(A) of the Agricultural Bioterrorism Pro-
tection Act of 2002 (7 U.S.C. 8401(e)(2)(A)) is
amended by inserting “, and appropriate training,”
after “have a legitimate need”.

(c) Covered Agencies.—

(1) Amendment to the Public Health
Service Act.—Section 351A(h)(2)(A) (42 U.S.C.
262a(h)(2)(A)) of the Public Health Service Act is
amended by inserting “the Department of Homeland
Security,” after “the Department of Agriculture.”
(2) Amendment to the Agricultural Bio-
terrorism Protection Act of 2002.—Section
212(h)(2)(A) of the Agricultural Bioterrorism Pro-
tection Act of 2002 (7 U.S.C. 8401(h)(2)(A)) is
amended by inserting “the Department of Homeland
Security,” after “the Department of Agriculture.”.

SEC. 102. SELECT AGENT PROGRAM REVIEW.

(a) In General.—The Secretary of Health and
Human Services, in consultation with the Secretary of Ag-
culture, shall enter into a contract with the National
Academy of Sciences to conduct a review of the select
agent program under section 351A of the Public Health
Service Act (42 U.S.C. 262a) and section 212 of the Agri-
cultural Bioterrorism Protection Act of 2002 (7 U.S.C.
8401). Such review shall focus on—

(1) the extent to which the program has en-
hanced biosecurity and biosafety in the United
States;

(2) the effects of the program on—

(A) international scientific collaboration;

and

(B) scientific advances in the United
States; and
(3) other issues as requested by the Secretary of Health and Human Services and the Secretary of Agriculture.

(b) Report; Recommendations.—Not later than 240 days after the date of enactment of this Act, the National Academy of Sciences shall submit a report to the Secretary of Health and Human Services, the Secretary of Agriculture, the Committee on Health, Education, Labor, and Pensions of the Senate, the Committee on Energy and Commerce of the House of Representatives, and other congressional committees of relevant interest, on the results of the review conducted under subsection (a). Such report shall include recommendations for improving the structure of the select agent program for—

(1) enhancing the biosecurity and biosafety of the United States;

(2) eliminating or reducing adverse effects of the program, if any, on—

(A) international scientific collaboration;

and

(B) scientific advances in the United States; and

(3) other issues as requested by the Secretary of Health and Human Services and the Secretary of Agriculture.
SEC. 103. REVISION OF THE LIST OF BIOLOGICAL AGENTS AND TOXINS.

(a) Amendment to the Public Health Service Act.—Section 351A(a)(1)(B)(i) of the Public Health Service Act (42 U.S.C. 262a(a)(1)(B)(i)) is amended—

(1) in subclause (III), by striking “; and” and inserting a semicolon;

(2) by redesignating subclause (IV) as subclause (VII); and

(3) by inserting after subclause (III) the following:

“(IV) whether the agent or toxin is endemic to the United States, as defined by the Secretary;

“(V) information available from biological risk assessments conducted by the Department of Homeland Security;

“(VI) newly discovered agents of disease, including genetically modified organisms or agents created synthetically; and”.

(b) Amendment to the Agricultural Bioterrorism Protection Act of 2002.—Section 212(a)(1)(B)(i) of the Agricultural Bioterrorism Protec-

(1) in subclause (III), by striking “; and” and inserting a semicolon;

(2) by redesignating subclause (IV) as subclause (VII); and

(3) by inserting after subclause (III) the following:

“(IV) whether the agent or toxin is endemic to the United States, as defined by the Secretary;

“(V) information available from biological risk assessments conducted by the Department of Homeland Security;

“(VI) newly discovered agents of disease, including genetically modified organisms or agents created synthetically; and”.

(c) Rule of Construction.—The amendments made by subsections (a) and (b) shall not be construed to preclude the listing of a biological agent or toxin that is endemic to the United States.
SEC. 104. SHARING INFORMATION WITH TRUSTED STATE PARTNERS.

(a) Amendment to the Public Health Service Act.—Section 351A(h)(5) of the Public Health Service Act (42 U.S.C. 262a(h)(5)) is amended—

(1) in subparagraph (A), by striking “; or” and inserting a semicolon;

(2) in subparagraph (B), by striking the period and inserting “; or”; and

(3) by inserting at the end the following:

“(C) to withhold information regarding a State that will assist with the State’s emergency preparedness planning from the health director (or equivalent State official) of such State, if such State has in place a law to protect against the further release of such information as determined by the Secretary.”.

(b) Amendment to the Agricultural Bioterrorism Protection Act of 2002.—Section 212(h)(5) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401(h)(5)) is amended—

(1) in subparagraph (A), by striking “; or” and inserting a semicolon;

(2) in subparagraph (B), by striking the period and inserting “; or”; and

(3) by inserting at the end the following:
“(C) to withhold information regarding a State that will assist with the State’s emergency preparedness planning from an elected or appointed senior State agricultural official or equivalent State official (such as a State veterinarian or a State plant health regulatory official) of such State, if such State has in place a law to protect against the further release of such information as determined by the Secretary.”.

SEC. 105. IMPROVEMENTS TO INVENTORYING AND MONITORING OF AGENTS.

(a) IMPROVED METHOD TO INVENTORY AND MONITOR LISTED BIOLOGICAL AGENTS.—Not later than 180 days after enactment of this Act, the Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, and in consultation with individuals with appropriate scientific expertise, shall issue guidance on inventorying and monitoring the biological agents listed under section 351A(a)(1) of the Public Health Service Act (42 U.S.C. 262a(a)(1)) and the biological agents listed under section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401(a)(1)).

(b) CONSIDERATIONS.—In issuing the guidance under subsection (a), the Secretaries shall consider—
(1) the effectiveness of measures to inventory
and monitor listed biological agents that can propa-
gate relative to the burden of these measures on lab-
ory personnel;

(2) qualitative and quantitative control proce-
dures for such listed agents, rather than only quan-
titative control procedures; and

(3) in what situations registered persons are re-
quired to keep inventory records.

SEC. 106. SMALLPOX DEFINITION CLARIFICATION.
Not later than 90 days after the date of enactment
of this Act, the Attorney General, in coordination with the
Secretary of Health and Human Services, shall issue pub-
lic guidance regarding how the Attorney General inter-
prets the scope of the statutory definition of “variola
virus” in section 175e of title 18, United States Code.

SEC. 107. PLAN FOR SURGE IN SAMPLES OF BIOLOGICAL
AGENTS AND TOXINS.
The Secretary of Health and Human Services, in co-
ordination with the Secretary of Agriculture and State of-
ficials, shall develop and disseminate guidelines for how
laboratories and laboratory personnel that do not regularly
test for listed agents and toxins (as such terms are defined
in section 351A of the Public Health Service Act (42
U.S.C. 262a) and section 212 of the Agricultural Bioter-
rorism Protection Act of 2002 (7 U.S.C. 8401)) may be rapidly accessed and utilized during emergencies in which laboratories and laboratory personnel that regularly test for such agents and toxins are overwhelmed by a surge of samples of such listed agents and toxins.

**TITLE II—BIOSAFETY IMPROVEMENTS**

**SEC. 201. IMPROVEMENT OF OVERSIGHT OF BIOCONTAINMENT LABORATORIES.**

(a) **DEFINITION.**—For purposes of this section, the term “high containment biological laboratory” means a laboratory that has Biosafety Level 3 or Biosafety Level 4 facilities, as defined by the Secretary of Health and Human Services and the Secretary of Agriculture.

(b) **EVALUATION.**—The Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, and in consultation with the Secretary of Defense and the Secretary of Homeland Security (referred to in this section as the “Secretaries”) shall, either directly or through a contract, evaluate national needs of, and oversight of, high containment biological laboratories.

(c) **CONSIDERATIONS.**—In conducting the evaluation under subsection (b), the Secretaries shall consider—

(1) whether the construction of high containment biological laboratories that are in existence or
planned as of the date of enactment of this Act, is likely to provide sufficient capacity for the needs of Government biodefense and infectious disease research;

(2) how laboratory capacity and lessons learned can be best shared across the biodefense and infectious disease research communities, domestically and internationally;

(3) whether guidance on laboratory infrastructure, commissioning, operation, and maintenance of such laboratories is adequate, and if such guidance is found to be inadequate, how to improve and streamline such guidance; and

(4) ways to improve and streamline the training of the personnel of such laboratories, including recommendations regarding the minimum standards for laboratory biosafety and biosecurity training under section 202.

(d) REPORT TO CONGRESS.—Not later than 240 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report on the findings and recommendations from the evaluation under this section.
SEC. 202. IMPROVEMENT OF TRAINING FOR LABORATORY PERSONNEL.

(a) DEFINITION.—For purposes of this section, the term “high containment biological laboratory” means a laboratory that has Biosafety Level 3 or Biosafety Level 4 facilities, as defined by the Secretary of Health and Human Services and the Secretary of Agriculture.

(b) DEVELOPMENT OF MINIMUM STANDARDS.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, and in coordination with the Secretary of Agriculture and scientific experts representing appropriate professional groups and international health organizations, shall develop minimum standards for laboratory biosafety and biosecurity training for relevant personnel of high containment biological laboratories. In developing such standards, the Secretary of Health and Human Services shall consider existing laboratory guidelines and training modules.

(c) REQUIREMENT FOR APPROVAL.—A person may not register with the Secretary of Health and Human Services or the Secretary of Agriculture for the possession, use, or transfer of listed agents in accordance with section 351A of the Public Health Service Act (42 U.S.C. 262a) and section 212 of the Agricultural Bioterrorism Protec-
tion Act of 2002 (7 U.S.C. 8401) unless the person pro-
vides to its appropriate personnel biosafety and biosecurity
training that meets the minimum standards under sub-
section (b) in addition to any other requirements deter-
mined appropriate by the Secretary of Health and Human
Services or the Secretary of Agriculture.

(d) DISSEMINATION.—The Secretary of Health and
Human Services, in coordination with the Secretary of Ag-
riculture, may disseminate the minimum standards under
subsection (b) for voluntary use, such as when use is not
required under subsection (b), in laboratories and aca-
demic programs in the United States and in other coun-
tries.

SEC. 203. BIOLOGICAL LABORATORY INCIDENT REPORTING
SYSTEM.

(a) IN GENERAL.—The Secretary of Health and
Human Services, in coordination with the Secretary of Ag-
riculture, (referred to in this section as the “Secretaries”)
shall establish an integrated Biological Laboratory Inci-
dent Reporting System through which personnel of biologi-
cal laboratories may voluntarily report biosafety or bio-
security incidents of concern and the Secretaries may
identify trends in such incidents and protocols for bio-
safety or biosecurity improvements. In developing such re-
porting system, the Secretaries shall consider options for
integrating existing voluntary and required reporting mechanisms.

(b) FUNCTIONS.—In implementing the reporting system under subsection (a), the Secretaries shall enter into a contract with a public or private entity that does not regulate biological laboratories to administer the reporting system. Such entity shall—

(1) receive and process incident reports;
(2) analyze, interpret incident data, and identify incident trends;
(3) issue alert messages within an appropriate time period;
(4) disseminate reports and other appropriate information, which shall not include facility-specific information;
(5) not have authority to direct corrective action or to initiate enforcement action;
(6) ensure anonymity of individuals reporting to the system, to the extent permitted by law; and
(7) conduct other activities as requested by the Secretaries.